510(k) Summary
As required by 21CFR 807.92(c)

510(k) Number: K121641

SEP 7 2012

Date Prepared: August 2, 2012

Submitter Information:

Submitter's Name/ Address:	American Medical Systems 10700 Bren Road W. Minnetonka, MN 55343
Contact Person:	Renee Mellum Sr. Regulatory Affairs Associate Tel: 952-930-6458 Fax: 952-930-5785 Renee.Mellum@AmericanMedicalSystems.com
Alternate Contact:	Josh Clarin Manager, Regulatory Affairs Tel: 952-939-7072 Fax: 952-930-5785 Josh.Clarin@AmericanMedicalSystems.com

Device Information:

Trade Name:	MiniArc® Pro Single-Incision Sling System
Common Name:	Surgical Mesh
Classification Name:	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Female, Single-Incision Mini-Sling
Class:	Class II / 21 CFR § 878.3300
Product Code:	PAH

Predicate Device:

MiniArc® Precise Single-Incision Sling System (K100807)

Device Description:

The MiniArc® Pro Sling System is designed to treat female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The sling is comprised of a piece of polypropylene monofilament mesh with polypropylene self-fixating tips (anchors), a mid-line mark, and elongation feedback system. The elongation feedback system is attached to the sling for use during intra-operative adjustment/tensioning and allows for objective measurement of sling elongation during the implant procedure. The sling is intended to remain in the body as a permanent implant with the polypropylene self-fixating tips providing short-term fixation prior to tissue in-growth. The elongation feedback system is intended to be removed prior to closure of the vaginal incision. The delivery tool (needle) is designed to interface with the self-fixating tips and deliver it to the obturator internus muscle, retaining the self-fixating tip until it is selectively released by the physician.

510(k) Summary
As required by 21CFR 807.92(c)

Indications for Use:

The MiniArc® Pro Single-Incision Sling System is intended for the placement of a sub-urethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Comparison to the Predicate Device:

The MiniArc Pro Single-Incision Sling System intended use and indication for use is identical to that of the predicate device. In addition, the MiniArc Pro Single-Incision Sling System utilizes many of the same materials, design principles and fundamental scientific technology as the predicate K100807.

Device Characteristic	Subject Device: MiniArc Pro	Predicate Device: MiniArc Precise K100807
Indications for Use	The MiniArc Pro Single-Incision Sling System is intended for the placement of a sub-urethral mesh for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).	The MiniArc Precise Single-Incision Sling System is intended for the placement of a sub-urethral mesh for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).
Device Design Mesh Assembly:		
• Mesh	Polypropylene, Type I monofilament	Polypropylene, Type I monofilament
•Self-Fixating Tip	Polypropylene, Type I monofilament	Polypropylene, Type I monofilament
• Midline Mark	Printed, Blue	Printed, Blue
Device Design Delivery Tool:		
• Handle	Polycarbonate with over-mold	Polycarbonate with over-mold
• Needle, material	Stainless Steel with molded barb guards	Stainless Steel with molded barb guards
Device Design Feedback System	Polypropylene aperture, backer plate, removal suture, removal tab	Not Present
Fundamental Technology	Self fixation urethral mesh sling	Self fixation urethral mesh sling
Procedure	Transobturator-like approach	Transobturator-like approach
Packaging Materials	PETG tray and Tyvek lid	PETG tray and Tyvek lid
Packaging Configuration	Single sterile barrier configuration	Single sterile barrier configuration

510(k) Summary
As required by 21CFR 807.92(c)

Device Characteristic	Subject Device: MiniArc Pro	Predicate Device: MiniArc Precise K100807
Sterilization	EO with SAL > 10^{-6}	EO with SAL > 10^{-6}

Summary of Non-Clinical Testing:

Bench testing was performed to support this submission. Results of the testing demonstrate that the MiniArc Pro Single-Incision Sling System meets product specification and performance requirements.

The following testing has been successfully completed:

- Sterilization
- Shelf Life
- Biocompatibility
- Performance Testing (Bench)
  - Feedback System Repeatability
  - Feedback System Attachment
  - Feedback System Dimensional
  - Feedback System Removal Force
  - Feedback System Stiffness
- Performance Testing (Cadaver)
  - Physician Questionnaire
  - Cadaver Evaluation

Clinical Testing:

No clinical testing was performed to support this Traditional Premarket Application.

Statement of Equivalence:

The MiniArc® Pro Single-Incision Sling System has the identical indications for use and fundamental scientific technology as the predicate device. Based on this and the design and engineering data provided in the pre-market notification, the MiniArc® Pro Single-Incision Sling System has been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Renee Mellum
Senior Regulatory Affairs Associate
American Medical Systems, Inc.
10700 Bren Road West
MINNETONKA MN 55343

SEP 7 2012

Re: K121641
Trade/Device Name: MiniArc® Pro Single-Incision Sling System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: August 3, 2012
Received: August 7, 2012

Dear Ms. Mellum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: ~~TBD~~ K121641

Device Name: MiniArc® Pro Single-Incision Sling System

Indications for Use:

The MiniArc® Pro Single-Incision Sling System is intended for the placement of a sub-urethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121641